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December 19, 2005

Division of Dockets Management (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, Maryland 20852.

**Re: Docket No. 2002N-0273- Substances Prohibited From use in
Animal Food or Feed**

To Whom It May Concern:

The California Grain and Feed Association (CGFA) is writing to comment on FDA Docket No. 2002N-0273, the proposed rule regarding bovine spongiform encephalopathy (BSE) and substances prohibited from use in animal food or feed. We represent 225 companies engaged in processing, manufacturing and distribution of grain and feed products in California as well some vertically integrated operations engaged in dairy or feedlot production and some dairy farmer owned cooperatives.

CGFA is strongly opposed to approving additional rules related to BSE and believes the proposed rules do not consider the animal, human and environmental health impacts resulting from their implementation. We believe these impacts to be most severe in California, the largest dairy state in the country. We further believe that the current regulatory framework provides a sufficient firewall to protect the public health which we stated previously in response to FDA Docket No. 2004N-0264, the agency's advanced notice or rulemaking regarding BSE.

Changes in the BSE Rules Are Unnecessary

CGFA does not believe that modifying the current BSE rules is necessary based on the incidence of infection. The comprehensive BSE surveillance program has provided clear and convincing evidence that the BSE risk in the U.S. is miniscule. There has only been one indigenous animal found positive for BSE out of nearly 550,000 of the highest risk cattle tested, the biggest percentage of which were California cattle. It has been estimated that this equates to one infection in over 15.2 million cattle. There are only 12 million cattle over the age of 30 months in the country, thus the infection rate is essentially zero. When this is coupled with the current Specified Risk Material (SRM) regulatory prohibitions the potential infection risk is so low as to not even be quantifiable.

California Specific Information

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Dairying is the number one agricultural sector in California. It is estimated that there are 1.7 million milking dairy cows in California with a similar number of head of replacement stock (calves and heifers). In a survey conducted recently by CGFA we found that California rendering companies and licensed dead haulers are picking up 168,176,472 pounds of adult cattle and 128,750,000 pounds of calves and other cattle under 30 months of age per year. This roughly equates to 140,150 adult cows and 321,875 calves and other cattle under thirty months of age per year using an average wait of 400 pounds per calf and 1200 pounds per adult cow.

In this same survey, renderers reported that the cost to pick up calves and not render them would increase by 71% for calves and 31% for adult cows. To pick up cows and attempt to remove brain and spinal cord was estimated to cost \$200 per adult cow (up from an average of \$126 per adult cow) or a 59% increase over the current fees charged for pick up. The increased costs are due to having to take carcasses and/or brain and spinal cord to landfills and the related tipping fees for using landfills as well as the loss of hides and meat and bone meal that could have otherwise been sold.

As the cost of pick rises, it is believed that California dairy farmers will seek other means of disposal resulting in lost throughput for California rendering companies.

Feasibility of Removal

Our renderers report serious concerns about being able to accomplish removal of brain and spinal cord. Removal of brain and spinal cord becomes even more problematic in California in the summer months when temperatures in the San Joaquin Valley, the state's largest dairymen's area, often reach 100 degrees F and occasionally reach 110 degrees F. Renderers often do not have access to cow carcasses for several days and when coupled with high temperatures, this results in significant deterioration making recovery of the animal and removal of brain and spinal cord difficult if not impossible. Even now, renderers report that only 50% of the carcasses are in a condition to remove the hides in the summer time and a carcass in this condition is also not suitable for brain and spinal cord removal.

The California rendering industry has also questioned whether or not the proposed regulations require complete removal of all brain and spinal cord

material. Even using the best methods of removal available some minute amount of prohibited material may remain resulting in potential enforcement action. What standards of removal will FDA establish and how will this new rule be enforced. Will there be testing to ensure compliance and will there be any tolerance established?

CGFA believes that removal of brain and spinal cord is quite infeasible and is not a workable approach for the California rendering industry.

Undesirable Untended Consequences

We believe that FDA is not considering all the undesirable unintended consequences of the rules as proposed. It appears the agency is ignoring animal and human health concerns as well as serious environmental concerns. We are concerned that FDA is not considering how daily mortality will be disposed of once the rules are in place. As the costs of disposal rise, cattle owners will look for disposal alternatives including abandonment, stock piling or burial of carcasses on the dairy. Carcasses that have deteriorated to the point that a renderer cannot remove the brain and spinal column will have to go to landfills. Incineration is time consuming and costly and the sheer numbers of daily mortality in California make this an unworkable and cost prohibitive disposal alternative.

California does not permit composting of cattle due to animal health concerns. California law does generally permit burial of animals on one's own property if such burial does not result in ground or surface water contamination. However, each county has separate environmental health regulations and in many counties burial would be prohibited notwithstanding the state law. Burial will be a legal solution for only a modest percentage of some dairy farmers and even in those cases such disposal will be a questionable disposal alternative from an environmental standpoint.

Although some landfills will take animal remains many do not. Our landfills are already overburdened and any regulatory scheme that significantly increases waste materials moving to landfills is ill conceived. In fact, landfills in California and many other states are under strict deadlines to reduce solid waste with specific statutory reduction goals. The proposed BSE rules fly in the face of this important public policy concern.

We also have animal health concerns. We believe that the new rules and the increasing cost burden they impose on the dairy industry will result in carcass dumping and disposal methods that fall outside the current closed loop provided

by the rendering industry. Even disposing of carcasses at landfills poses animal health risks. As carcasses are abandoned, buried, or taken to landfills other pathogens and diseases are being spread far and wide risking both animal and human health. It is best to have a regulatory environment that promotes disposal through licensed renderers whose processes provide for pathogen free recycled products and the best opportunity for FDA to test and monitor the highest risk animals as the current surveillance program now does.

Voluntary BMP's and High Rate of Compliance with Existing Rules

The proposed BSE rules do not recognize the good efforts of the feed and rendering industries already underway to reduce the risk of BSE infection. In California according to our state Department of Food and Agriculture, ruminant feed manufacturers have removed all ruminant based feeds (i.e. MBM) from their feed manufacturing facilities with only a couple of exceptions and in those facilities there are dedicated lines, equipment and storage. Feed mills in California took this step voluntarily as a Best Management Practice (BMP) even though they may produce some non-ruminant feeds. These BMP's were implemented back in 1997 when the issue of BSE first surfaced.

It is worthy of note that FDA's Center for Veterinary Medicine recently released the latest compliance rates relative to the current BSE rules and requirements and the results of the most recent inspections show a very high degree of compliance. Only three feed mills out of the several thousand handling prohibited materials were classified as OAI (Official Action Indicated). In California, we have always had excellent compliance with the existing rules which is borne out by the inspection records. The high level of compliance with the existing rules shows the industry's commitment to animal and the public health, but the new rules do not recognize these efforts nor the fact that such compliance reduces further what is already a near zero risk of infection.

Economic Burden on the Dairy and Beef Industries

CGFA is concerned about the additional economic burden the new rules will place on California's dairy and beef industries. Much of the increased costs resulting from the proposed rules will be borne by the dairy farmer. In California, based on the input from renderers on increased carcass pick-up fees, the additional costs for California dairy farmers, feedlots and beef cattle producers will exceed \$10,000,000. This is no small economic impact.

California Obstacles to Plant Modification

The agency should not assume that the industry can adjust to rules overnight. Rendering plant and equipment modifications will be necessary and renderers will need to find disposal alternatives. Not all landfills take animal carcasses and those that do require special timing of deliveries all of which would need to be worked out by agreement.

We are very concerned that FDA does not have an understanding of what it will take for the rendering and related industries to comply with the existing rules and the obstacles other regulatory agencies (state and regional) require when making plant modifications. Making plant modifications in California is not an easy task and is very time consuming. Plant modifications require land use permit changes as well as air permitting related to emissions and any new equipment. It can easily take a year and as much as two years to obtain the necessary air and use permits for a plant modification. Environmental reports may need to be completed and there are engineering costs to also take into consideration. And, there are waste water discharge permits and considerations that also come into play when building a new plant or modifying an existing one.

Additionally, rendering plants in California are allowed to emit nuisance odors under the laws of the state so long as plant operations do not change significantly. CGFA is concerned that the new rules might result in plant changes that would jeopardize this important nuisance odor statute.

FDA needs to consider that approval and publication of any new rules with a short time frame before they take effect will result in immediate animal disposal problems. Even when we have experienced abnormally high dairy mortalities due to hot weather we have had serious stockpiling of dead stock because we do not have the rendering capacity to handle the excess mortality. As indicated above, California's daily cattle mortality is several hundred head of adult cows per day plus daily calf mortality at several fold that amount. As deteriorating carcasses back up in the system the problem only worsens. Remember too that rendering plants in California have daily emission limits that cannot be exceeded and any event that causes an unexpected backlog of carcasses can be very difficult if not impossible to resolve. We have on occasion had to have the governor use the emergency powers of the office to resolve an animal disposal crisis.

If rule changes are to be made, significant advance notice to the industry will be necessary.

Conclusion

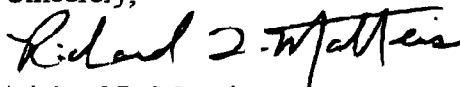
In summation, CGFA opposes any modifications to the existing rules. We also believe that ruminant meat and bone meal can be safely fed to non-ruminant species and, therefore, any BSE regulatory scheme should not unnecessarily inhibit such use. In times of increasing solid waste it is good public policy to facilitate recycling of all wastes and by-products that can be recycled not impede such recycling.

We do not believe the potential BSE infection risk which is nearly zero warrants any regulatory changes. In fact, we believe there will be serious detrimental animal, public and environmental health issues caused by the approval of the proposed rules.

Even if one were to assume the BSE infection risk justified new restrictions, the proposed rules are not a solution. They are half of a solution because they do not address the very real carcass disposal problem they will cause if approved and implemented. The agency and other federal agencies need to address the disposal issue and provide funding and disposal alternatives for daily cattle mortality.

We thank for the opportunity to comment and for considering our views.

Sincerely,



Richard L. Matteis
Executive Vice President